Supreme Court, U. S.
FILED
SEP 23 1980
MICHAEL RODAK, JR., CLERK

No. 80-259

In the Supreme Court of the United States

OCTOBER TERM, 1979

GLEN L. RUTHERFORD, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the court of appeals correctly determined that a group of drugs commonly referred to as Laetrile is not exempt from the premarketing clearance requirements of the Federal Food, Drug, and Cosmetic Act by operation of the Act's 1962 grandfather clause.

2. Whether the court of appeals correctly determined that the Federal Food, Drug, and Cosmetic Act does not violate any constitutional right of privacy by prohibiting the interstate distribution of Laetrile until the drug is approved as safe and effective pursuant to the Act.

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*Pursuant to Rule 40.3 of the Rules of this Court, Patricia Roberts Harris, Secretary of Health and Human Services, and Jere E. Goyan, Commissioner of the Food and Drug Administration, are substituted for the additional respondents identified in the petition (Pet. ii).

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OPINIONS BELOW

The opinion of the court of appeals on remand from this Court (Pet. App. A-1 to A-11) is reported at 616 F. 2d 455. This Court's prior decision (442 U.S. 544) reversed and remanded an earlier opinion by the court of appeals (582 F. 2d 1234) that, in turn, affirmed the district court's opinion (438 F. Supp. 1287).

JURISDICTION

The judgment of the court of appeals was entered on February 19, 1980. A petition for rehearing was denied on April 28, 1980 (Pet. App. A-13). The petition for a writ of certiorari was filed July 28, 1980. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTES INVOLVED

Section 107(c)(4) of the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 789 ("1962 grandfather clause") is set forth at Pet. 4-5.

Pertinent portions of Section 201(p) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(p), are set forth at Pet. 4.

Section 505 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 355, provides in part:

> (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.
>
> (b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full report reports of investigations

which have been made to show whether or not such drug is safe for use and whether such drug is effective in use * * *

* * * * *

(d) If the Secretary finds * * * that (1) the investigations * * * required to be submitted to the Secretary * * * do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests * * * do not show that such drug is safe for use under such conditions; * * * (4) * * * he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) * * * there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. * * * As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use

prescribed, recommended or suggested in the labeling or proposed labeling thereof.

* * * * *

(i) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing * * *.

STATEMENT

This action, which was instituted by cancer patients in 1975, seeks to prevent the government from interfering with the interstate sale or distribution of a drug called Laetrile. In an order entered August 14, 1975, and amended October 10, 1975, the district court enjoined the government from preventing the purchase and subsequent interstate movement of a limited quantity of Laetrile for Glen L. Rutherford, one of the plaintiffs. *Rutherford* v. *United States*, 399 F. Supp. 1208, 1215 (W.D. Okla. 1975).[1] On appeal, the Tenth Circuit did not disturb the injunction, but instructed the district court to remand the

[1] The district court subsequently entered similar orders on behalf of other plaintiffs.

case to the Commissioner of Food and Drugs ("Commissioner") for the development of an administrative record addressing the questions whether Laetrile is a "new drug" within the meaning of Section 201(p) of the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. 321(p), and, if so, whether it is exempt from the Act's premarketing approval requirements by virtue of the Act's 1962 grandfather clause. *Rutherford* v. *United States,* 542 F. 2d 1137 (10th Cir. 1976).[2]

After an administrative proceeding, the Commissioner concluded that Laetrile is a "drug" as defined in the Act, and a "new drug" within the meaning of Section 201(p) of the Act. 42 Fed. Reg. 39768-39772, 39801-39803 (1977). He found that Laetrile does not satisfy the premarketing approval requirements for new drugs in Section 505 of the Act, 21 U.S.C. 355, because it does not meet the statutory safety and effectiveness requirements. The Commissioner found that there is "an absence of scientifically sound data upon which experts * * * could base an opinion that Laetrile is safe for use in man" (42 Fed. Reg. 39786), and that "[t]here are no clinical investigations of Laetrile's effectiveness, published or otherwise, which are even arguably adequate and well-controlled" (*id.* at 39776).

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[2]The Drug Amendments of 1962 contain a grandfather clause that excludes from the definition of "new drug" any drug that, on October 9, 1962 (the day immediately preceding the enactment of the 1962 Amendments): "(A) was commercially used or sold in the United States, (B) was not a new drug [under the 1938 Act] * * * and (C) was not covered by an effective [new drug application]." Pub. L. No. 87-781, Section 107(c)(4), 76 Stat. 789.

The Act also contains a 1938 grandfather clause (included in Section 201(p) of the Act, 21 U.S.C. 321(p)). The availability of that exemption for Laetrile is not in issue here, although it was addressed by the Commissioner and the district court. See 42 Fed. Reg. 39788-39790 (1977); *Rutherford* v. *United States*, 438 F. Supp. 1287, 1298 (W.D. Okla. 1977).

The Commissioner further found that Laetrile does not meet the statutory criteria of the 1962 grandfather clause for the following reasons: (1) The drug presently termed "Laetrile" was not shown to be the same drug used during the applicable prior period; (2) the prior labeling and representations concerning use are not identical to the representations associated with the presently marketed drugs; (3) Laetrile was not commercially used or sold on the grandfather date; and (4) experts did not generally recognize it as safe on that date. 42 Fed. Reg. 39787-39795.

On review of the Commissioner's decision, the district court upheld his determination that Laetrile is a drug, and further held (438 F. Supp. at 1293) that "the evidence of record does not render the Commissioner's conclusion that Laetrile is not 'generally recognized as safe and effective' arbitrary and capricious." The court concluded, however, that the drug is exempt from the Act's premarketing approval requirements by virtue of the 1962 grandfather clause. In reaching this conclusion, the court set aside each of the Commissioner's factual findings on the issue. 438 F. Supp. at 1295-1298. The court further concluded (438 F. Supp. at 1301; footnote omitted) that "[b]y denying the right to use a nontoxic substance in connection with one's own personal health-care, FDA has offended the constitutional right of privacy."[3]

The court of appeals, without addressing either the statutory or the constitutional ground on which the district court relied, held (582 F. 2d 1234, 1237) that "the 'safety' and 'effectiveness' requirements of the statute as

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[3]In reaching this conclusion the court expressly rejected (438 F. Supp. at 1296-1298 nn. 18, 23-24) the Commissioner's factual finding (42 Fed. Reg. 39786-39787, 39806) that Laetrile has a known toxicity that has not been fully investigated.

now written have no application to terminally ill cancer patients who desire to take [Laetrile] intravenously."

On review, this Court reversed, holding that there is no express or implied exception from the Act for drugs used by the terminally ill. 442 U.S. 544 (1979). In reaching this decision, the Court noted the all-inclusive language of the statute (442 U.S. at 551) and congressional approval of FDA's pre-1962 policy of considering effectiveness when passing on the safety of drugs prescribed for life-threatening diseases such as cancer. 442 U.S. at 553-554 & nn.9, 10. The Court further observed (442 U.S. at 549-550) that the Commissioner applied the statutory criteria delineated in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629-630 (1973), in finding that Laetrile was a new drug because it was not generally recognized as safe and effective. The Court remanded for consideration of the constitutional and grandfather clause issues reached by the district court. 442 U.S. at 559 n.18.

On remand from this Court, the court of appeals held that the proponents of Laetrile had not satisfied the Act's premarketing clearance requirements, and that the record did not support a conclusion that Laetrile satisfied the conditions of the 1962 grandfather clause (Pet. App. A-10 to A-11). Concerning the constitutional issue, the court of appeals held (*id.* at A-8) that while a patient has a right to undergo or forego medical treatment, the selection of a particular medical treatment or medication "is within the area of governmental interest in protecting public health." Thus, the Act's premarketing requirements are a legitimate exercise of congressional authority that does not offend any constitutional right of privacy (Pet. App. A-7 to A-9).

ARGUMENT

The opinion of the court of appeals is correct, consistent with prior caselaw, and presents no issue warranting a second review by this Court.

1. a. The court of appeals correctly held that the group of drugs commonly referred to as Laetrile is not exempt from the premarketing clearance requirements of the Federal Food, Drug, and Cosmetic Act by operation of the Act's 1962 grandfather clause.

That Act prohibits the introduction of any new drug into interstate commerce without approval by the Commissioner based upon adequate scientific evidence that the drug is both effective for its intended use and safe. 21 U.S.C. 355(a), (d) and 321(p)(1); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612-615 (1973). (Provisions are made in Section 505(i) of the Act, 21 U.S.C. 355(i), however, for the investigational use of a new drug prior to approval.)

The effectiveness requirement was added by the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, which also included a grandfather clause that permits the continued marketing of certain established drugs that were being lawfully marketed in 1962. Those seeking to qualify a drug for exemption under the 1962 grandfather clause must establish (1) that the present drug is chemically identical to a drug in existence on the grandfather date, October 9, 1962; (2) that the drug was commercially available in 1962; (3) that the drug was generally recognized by experts as safe for its intended use; (4) that the present labeling for the drug is the same as the labeling used for it in 1962; and (5) that the drug was not covered in 1962 by an effective new drug application under the 1938 Act. Section 107(c)(4) of the Drug Amendments of 1962, 76 Stat. 789 (Pet. 4-5).

b. The Commissioner found (42 Fed. Reg. 39790-39795 (1977)) that Laetrile failed to meet all but the last of the five requirements and thus failed to qualify for an exemption under the 1962 grandfather clause. That determination is entitled to stand because, as shown below, it is supported by substantial evidence and is not arbitrary or capricious. *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 413-414 (1971).[4] In any event, review by this Court of the essentially factual questions (Pet. 18-19) raised by petitioners in their attack on the grandfather clause determination is inappropriate. See *Mobil Oil Corp.* v. *FPC*, 417 U.S. 283, 309-310 (1974); *United States* v. *Johnston*, 268 U.S. 220, 227 (1925).[5]

(1) *Composition*. First, the Commissioner properly found that the composition of the different substances referred to as Laetrile both before and after 1962 varied

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[4]Petitioners erroneously argue (Pet. 20) that the court of appeals erred by assuming that the burden of proof with respect to the grandfather clause rested on petitioners rather than the FDA. The plain language of the grandfather clause dictates that one seeking to gain an exemption under the clause must prove that he satisfies each of its prerequisites.

A fuller discussion of the evidence and reasoning supporting the Commissioner's findings as to each of the grandfather clause requirements is contained in the Brief for the United States at 36-52, *United States* v. *Rutherford*, 442 U.S. 544 (1979).

[5]Petitioners' attacks (Pet. 20-23) on the propriety of the administrative procedures followed by the FDA are not properly before the Court. Petitioners raised such questions during the first appeals to the court of appeals, and that court acknowledged the difficulties facing the agency under the circumstances of this case and did not fault it for the procedures employed. 582 F. 2d at 1236. Petitioners did not challenge the rejection of their procedural claims in their cross-petition for a writ of certiorari, which was denied. *Rutherford* v. *United States*, 439 U.S. 1128 (1979). Moreover, they do not now present such claims as a question for review (Pet. i).

considerably, and that the 1962 formulations differed from the formulations currently in use. 42 Fed. Reg. 39791.[6] Consequently, he determined that the proponents of Laetrile had failed to sustain the burden of showing that Laetrile as presently constituted was in use on October 9, 1962. *Ibid.* As the Commissioner noted, the fact that a drug used or sold on October 9, 1962, has some ingredients in common with a drug used or sold today would not establish identity of composition sufficient to satisfy the requirements of the grandfather clause. *Ibid.* A change in any of the ingredients, including inactive ingredients, or in the proportion of the ingredients, will make a drug a "new drug." See 21 C.F.R. 310.3(h); *Premo Pharmaceutical Laboratories, Inc.* v. *United States,* No. 79-6227 (2d Cir. July 29, 1980), slip op. 4713; *United States* v. *An Article of Drug* * * * *"Entrol-C Medicated,"* 513 F. 2d 1127, 1130 n.7 (9th Cir. 1975).

(2) *Commercial availability.* Commercial availability means that the drug has been "openly and readily available and broadly distributed in the ordinary course of business" and that there was no "restriction to investigational use." *Durovic* v. *Richardson,* 479 F. 2d 242, 248 (7th Cir.), cert. denied, 414 U.S. 944 (1973). Unless a drug was available generally for commercial use on October 9, 1962, the manufacturer lacks the reliance interest recognized by Congress as warranting a grandfather exception to the requirement of effectiveness. The administrative record fully supports the Commissioner's conclusions that Laetrile, as of October 9, 1962, was not openly and readily available and was not broadly

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[6]Laboratory analyses of drugs called Laetrile have often revealed both variances from labeled composition and variations in component parts and in the percentage of amygdalin, a principal ingredient, present (*ibid.*).

distributed in the ordinary course of business, but was in fact restricted to investigational use. 42 Fed. Reg. 39791-39792.[7]

(3) *Safety*. The 1962 grandfather clause, by its exclusion of drugs that were "new drugs" as defined in Section 201(p) of the pre-existing Act (52 Stat. 1041-1042), requires a drug to have been generally recognized as safe under its labeled conditions of use on October 9, 1962. This, in turn, requires that there must have existed on October 9, 1962, "investigations * * * includ[ing] adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use." Section 505(d)(1) of the Act, 21 U.S.C. 355(d)(1); *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973) ("the reach of scientific inquiry under both § 505(d) and § 201(p) is precisely the same"). Unless data from such tests were available in the scientific literature, there could be no basis for general recognition of safety among experts. *Weinberger* v. *Hynson, Westcott & Dunning, Inc., supra*; see also, *e.g., United States* v. *41 Cases, More or Less*, 420 F. 2d 1126, 1130 (5th Cir. 1970).

The record clearly indicates the absence in 1962 of any general recognition among qualified experts of Laetrile's safety, or indeed of any familiarity at all with the substances then referred to as "Laetrile."[8] Indeed, this

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[7]As the Commissioner noted (42 Fed. Reg. 39791-39792) statements and actions of Dr. Ernst T. Krebs, Sr., a developer of a drug to which he gave the name "Laetrile," and his son, Ernst T. Krebs, Jr., one of Laetrile's leading proponents, make it clear that pre-1962 distribution of drugs under that name was related to investigational use and not commercial sales.

[8]One serious obstacle to general recognition of Laetrile's safety was the pre-1962 variability in its composition and the varied conditions of use recommended in its labeling, which made it impossible to identify a single, uniform drug whose composition was "generally recognized" as safe "for use under the conditions prescribed,

Court has already held, in its earlier review of this case (442 U.S. at 549), that the Commissioner correctly applied the statutory criteria in concluding that there were no adequate, well-controlled scientific studies of Laetrile's safety. The Commissioner's finding that Laetrile was not generally recognized by experts as safe on October 9, 1962, did not, however, rest solely on the absence of scientifically developed data indicative of the drug's safety. It was also based on testimony of some of the nation's leading cancer scientists that Laetrile presents significant hazards to persons to whom it is administered. 42 Fed. Reg. 39786-39787.[9]

(4) *Labeling*. The Commissioner's finding that "Laetrile as now known is not intended solely for use under conditions recommended in labeling on October 9, 1962" (42 Fed. Reg. 39793 is supported by substantial

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recommended, or suggested in [its] labeling." Section 201(p)(1), 52 Stat. 1041-1042, 21 U.S.C. (1958 ed.) 321(p)(1); 42 Fed. Reg. 39790 (1977).

[9]Petitioners' contention (Pet. 25) that the FDA's approval of anticancer drugs with harmful side-effects demonstrates that it "has not even-handedly and non-discriminatorily applied to Laetrile the same standards by which it measures other anticancer drugs for 'safety' " is based on a misunderstanding of the applicable concept of drug safety. A drug is "safe" within the meaning of the Act if its expected therapeutic benefits outweigh the risks incurred. No drug is completely "safe" in the lay person's sense of the word, since every drug—even aspirin—involves risk. See L. Goodman & A. Gilman, *The Pharmacological Basis of Therapeutics* 325-339 (5th ed. 1975).

In the case of a drug, such as Laetrile, offered for the treatment of a life-threatening disease, lack of effectiveness not only means that there is nothing to balance against any risks: it is itself a source of risk. Patients may be led to forsake effective conventional treatments for something that will not help them. As this Court noted in its earlier opinion in this case (442 U.S. at 553-554 & nn.9, 10), the FDA's consideration of effectiveness as a criterion for the safety of drugs offered for the treatment of life-threatening diseases has congressional approval.

record evidence. *Id.* at 39792-39793. This included evidence that, in contrast to the labeling suggested by Ernst Krebs, Jr., on October 3, 1962, Laetrile was described after 1962 as a therapy that could and should be used to the exclusion of other cancer therapies. *Id.* at 39793. There was also evidence that oral administration of Laetrile first appeared after 1962 (*id.* at 39792-39793), and that suggested dosages have ranged from 1.5 grams to more than 9 grams, with no scientific rationale to account for the differing recommendations. *Ibid.* Indeed, the record indicates an absence of any uniform standard or generally recognized labeling either before or after 1962. *Ibid.*

2. In addressing the constitutional issue, the court of appeals stated (Pet. App. A-7 to A-8; citations omitted):

> It would serve no useful purpose to review the series of Supreme Court opinions treating the privacy issue * * *. It is apparent in the context with which we are here concerned that the decision by the patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health. The premarketing requirement of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355, is an exercise of Congressional authority to limit the patient's choice of medication. This is clear under the decisions referred to above.

Petitioners nevertheless contend (Pet. 28-42) that, in the words of the district court (438 F. Supp. at 1301; footnote omitted), "[b]y denying the right to use a nontoxic substance in connection with one's own personal health-care, FDA has offended the constitutional right of privacy." This contention lacks merit because it is based on an erroneous claim that Laetrile is nontoxic, on a

misunderstanding of the privacy interests cognizable under the Constitution, and on a failure to acknowledge the compelling governmental interests that would justify restrictions on importation and interstate distribution of Laetrile even assuming that there were a constitutional right of access to the drugs of one's choice.[10]

a. The district court's holding was premised on its unwarranted belief, contrary to the well-supported findings of the Commissioner (42 Fed. Reg. 39786-39787 (1977)), that Laetrile has been shown to be nontoxic. The court reached its conclusion by an improper reweighing of the evidence in the administrative record. It relied heavily on the anecdotal experiences of a handful of Laetrile practitioners and discounted the testimony of experts, credited by the Commissioner, which indicated that Laetrile is toxic in its oral form and that it had not been adequately tested for toxicity in any form. *Id.* at 39786-39787, 39802-39803, 39805.[11]

b. Even if Laetrile were not toxic, the court of appeals correctly held that there is no constitutional right to take any particular drug or class of drugs for medical purposes. The assertion of such a right challenges not only the Commissioner's ruling in this case but the Federal Food, Drug, and Cosmetic Act itself, as well as the centuries-old Anglo-American tradition of government protection of the public from foods and drugs that are unsafe, worthless, or fraudulent.

Petitioners essentially contend (Pet. 30, 33-39) that their asserted right of access to interstate shipments of Laetrile

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[10]For a fuller discussion of the constitutional issue, see the Brief for the United States at 52-75, *United States* v. *Rutherford, supra.*

[11]For a fuller discussion of the toxicity question, see the Brief for the United States at 53-56, *United States* v. *Rutherford, supra.*

comes within the constitutional right of privacy recognized in *Griswold* v. *Connecticut*, 381 U.S. 479 (1965), and a subsequent line of cases that this Court has characterized as protecting the individual's interest in making independent decisions in " 'matters relating to marriage, procreation, contraception, family relationships, and child rearing and education.' " *Whalen* v. *Roe*, 429 U.S. 589, 600 n.26 (1977), quoting *Paul* v. *Davis*, 424 U.S. 693, 713 (1976).

A right of caring for one's health by obtaining a particular drug without government hindrance does not fall within any of those categories and does not involve the kind of decision with which those cases were concerned. Indeed, those cases, which concern abortion and contraception laws, make it clear that even the recognized constitutional right of privacy in matters relating to marriage and procreation may be restricted in the interest of protecting the health of the persons concerned. See, *e.g.*, *Roe* v. *Wade*, 410 U.S. 113, 154, 162-164 (1973); *Doe* v. *Bolton*, 410 U.S. 179, 189 (1973); *Planned Parenthood of Missouri* v. *Danforth*, 428 U.S. 52 (1976); *Carey* v. *Population Services International*, 431 U.S. 678, 685-686 (1977). Moreover, in *Whalen* v. *Roe*, *supra*, a case concerning government-mandated procedures for prescribing certain drugs that had both recognized therapeutic uses and a potential for abuse, this Court observed (429 U.S. at 603) that a state "no doubt could prohibit entirely" the use of such drugs. *A fortiori* where a drug like Laetrile, with some demonstrated risks and no recognized medical uses, is concerned, no constitutional right of privacy guarantees access to supplies imported or marketed through interstate commerce. See *People* v. *Privitera*, 23 Cal. 3d 697, 591 P.2d 919, 153 Cal. Rptr. 431, cert. denied, 444 U.S. 949 (1979) (reaching the same conclusion respecting Laetrile as the court of appeals here).

c. Even if the constitutional right to privacy were held to include a right to take particular drugs for medical purposes, petitioners' claim would lack merit, because even "fundamental" rights may be restricted if the restrictions are justified by a "compelling" governmental interest. *Roe* v. *Wade, supra*, 410 U.S. at 155; *Carey* v. *Population Services International, supra*, 431 U.S. at 686.

The government has a compelling interest (1) in maintaining the confidence of the public and the medical profession in the safety and efficacy of the marketed drug supply; (2) in assuring that persons suffering from cancer, in both its early and late stages, are not deterred by the availability of an unproven drug such as Laetrile from seeking timely treatment by therapies of proven effectiveness; and (3) in assuring that cancer patients and their families are not defrauded by the promotion of costly but ineffective drugs.

Prohibiting the importation and interstate distribution of Laetrile until its safety and effectiveness are proven by reliable tests[12] is a reasonable means of effectuating those interests. And contrary to petitioners' contentions (Pet. 36-37), these restrictions are reasonable even where the drug is sought by "terminally ill" patients, a class which, as this Court has recognized (442 U.S. at 556), is almost impossible to define except in retrospect. Making available a limited supply of Laetrile to the "terminally ill" might suggest the drug had therapeutic value and induce patients who in fact have curable cancers to forsake therapies that could help them.

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[12]The government's position is merely that Laetrile, like all other new drugs, must satisfy the requirements of the Federal Food, Drug, and Cosmetic Act before it is marketed. The Commissioner has approved an application by the National Cancer Institute to conduct clinical testing of Laetrile. See Food Drug Cos. L. Rep. (CCH) para. 40,084 (Jan. 28, 1980).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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SEPTEMBER 1980

DOJ-1980-09